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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,775	10/29/1999	JONATHAN A. BARD	44743-AA-PCT	7729

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/430,775	BARD ET AL.	
	Examiner	Art Unit	
	Basi N [illegible]	1646	

-- The MAILING DATE of this c mmunication appears n the cover sheet with the c rrespondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *147-153* is/are pending in the application.

4a) Of the above claim(s) 149,150 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *147,148 and 151-153* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5*.
4) ☒ Interview Summary (PTO-413) Paper No(s). *7*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The preliminary amendment filed 6/26/00 has been entered.

2. Applicant's election with traverse of Group I (claims 147-148 and 151-153) in Paper No. 7 (8/18/03) is acknowledged. The traversal is on the ground(s) that the methods of Invention II and III are not independent of Group I, and therefore do not define patentability distinct inventions. Further Applicant argues that a search of the inventions can be made without serious burden on the Examiner. Applicant's arguments have been fully considered but not found persuasive.

Group I, claims 147-148 and 151-153, drawn to method of obtaining a composition which comprises determining whether a chemical compound binds a human Y4 receptor expressed on the surface of a mammalian cell transfected with a vector adapted for expressing the vector in the cell.

Group II, claims 149 and 151-153, drawn to method of obtaining a composition which comprises determining whether a chemical compound binds to and activates a human Y4 receptor expressed on the surface of a mammalian cell transfected with a vector adapted for expressing the vector in the cell.

Group III, claims 150 and 151-153, drawn to method of obtaining a composition which comprises determining whether a chemical compound binds to and prevents activation of a human Y4 receptor expressed on the surface of a mammalian cell transfected with a vector adapted for expressing the vector in the cell.

The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions I-III are distinct because they are independent, using separate method steps, and having different effects. The method of Group I obtains a compound which merely binds to the human Y4 receptor, said compound does not require it activate human Y4 receptor (Group II) or prevent activation of human Y4 receptor (Group III). The compounds of Group I may bind to Y4 receptor and have no affect on activation or inactivation of said receptor, e.g. antibody. The methods of Groups II and III obtain distinct classes of compounds that either activate or inactivate human Y4 receptor. The three Groups of methods obtain distinct classes of compounds, which a have different affects. Also, a search of Groups I-III would not be co-extensive particularly with regard to the literature search. An examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner. Claims 149-150 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Objections

3. The disclosure is objected to because of the following informalities:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78) as well as the relationship of instant application to the

parent. Parent Application 08/495,695, is now U.S. Patent Number 5,976,814, issued November 2, 1999, and must be indicated as such. Also specific reference to the prior application(s) must be in the first sentence of the specification, Applicant has added the reference following the heading "Background of the Invention". Appropriate correction is required.

4. Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). On page 11, Applicant has written "Brief Description of the Figures".

Appropriate correction is required.

5. The drawings are objected to because the figures should be labeled as Figure 1A, 1B, 1C, 1D, 1E, 2A, 2B, 2C, 3A, 3B, 3C, 3D or the equivalent, as required by 37 C.F.R. § 1.84 (u)(1). The Figures must also be described in the Brief Description of the Drawings as Figures 1A-E, Figures 2A-C, figures 3A-D etc. Appropriate correction is required.

Appropriate correction of the drawing as indicated by examiner in this Office action and as indicated by the draftsperson (PTO 948 attached) are required.

Corrections to drawings cannot be held in abeyance. Applicant must submit proposed drawing corrections in response to the requirement in the Office action.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

6. The disclosure is objected to because of the following informalities:

Nucleotide sequences e.g. on page 52, lines 24-25 must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Correction is required throughout the specification.

7. Applicants are advised that the ATCC has moved from Rockville, MD to Manassas, VA, effective March 23, 1998. The correct address is now:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

The specification should be amended to reflect the address for the ATCC.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 147-148 and 151-153 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 147-148 are indefinite because the name human Y4 receptor does not provide any structural limitation on the claim and the metes and bounds of the claim

cannot be determined. It is unclear what is a Y4 receptor. It is suggested, to overcome the rejection, human Y4 be identified by SEQ ID NO.

The term "substantially" in claim 151 is a relative terms which renders the claim indefinite. The term "substantially identical to the amino acid sequence shown in Figure 1 (SEQ ID NO:2)" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear when an amino acid sequence is substantially identical to the amino acid sequence shown in Figure 1 (SEQ ID NO:2) as compared to when it is not substantially identical to the amino acid sequence shown in Figure 1 (SEQ ID NO:2).

Claims 151, 152 and 153 are rejected for depending on the non-elected invention of claims 149 and 150. Dependency on non-elected invention must be amended.

Further claims 151-153 are rejected for depending upon indefinite base (or intermediate) claim and fail to resolve the issues raised above..

9. ***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 147-148 and 151-153 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of obtaining a composition,

which comprises determining whether a chemical compound binds to a human Y4 receptor expressed on the surface of a mammalian cell transfected with a vector adapted for expressing the receptor in the cell, wherein the chemical compound binds to a Y4 receptor encoded by the nucleotide sequence as set forth in SEQ ID NO:1 or encoding the polypeptide of SEQ ID NO:2 does not reasonably provide enablement for said methods using other Y4 receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification has disclosed human Y4 receptors identified by SEQ ID NO: 1, 2,. The name "human Y4 receptor" does not serve to sufficiently characterize and enable other proteins encompassed by the claims because the only Y4 receptors described or defined are identified by particular sequences. Further the specification does not teach how to use a commensurate number of compounds that may bind inactive Y4 receptors. The name human Y4 receptor does not disclose any structural and functional features encompassed by said name, then it accordingly follows that the specification does not adequately teach how to produce and use receptor encompassed by the term Y4 receptor.

While the person of ordinary skill in the art would, in light of the specification be able to use the Y4 receptor of SEQ ID NO:2 in claimed method, other receptors embraced by the name Y4 receptor or receptors substantially identical to SEQ ID NO:2 may completely unrelated to the protein of SEQ ID NO:2 or even be inactive. The scope of the claims, which encompass other receptor, apart from that disclosed in SEQ

ID NO:2, are not enabled by the disclosure. The disclosure does not teach how to make or identify such variants, or to use a commensurate number of the Y4 receptors which did not share the functional properties encompassed by the receptor disclosed in SEQ ID NO:2. Due to the large quantity of experimentation necessary to identify the polypeptides used in instant method, the lack of direction/guidance presented in the specification regarding the identification, purification, isolation and characterization of said polypeptides, the unpredictability of the effects of mutation on the structure and function of proteins (since mutations of SEQ ID NO:2 are also encompassed by the claim), and the breadth of the claim which fail to recite structural and functional limitations, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

9. Claims 147,148151 and 153 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Claims are drawn to a method of obtaining a composition which comprises determining whether a chemical compound binds to a human Y4 receptor, or a receptor

which has an amino acid sequence substantially identical to the amino acid sequence shown in Figure 1 (SEQ ID NO:2

The specification discloses an isolated the human Y4 receptor (SEQ ID NO:2) encoded by the polynucleotide of SEQ ID NO:1. The instant disclosure of one distinct polypeptide does not adequately describe the scope of the use of claimed genus, which encompasses a substantial variety of subgenera including full-length, truncated, fusion polypeptides and variants thereof. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by an amino acid sequence, falling within the scope of the genus or of a recitation of structural and functional features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. The fusion polypeptides, fragments and variants encompassed by the claims do not disclose the critical technical feature of the claimed invention or its relationship to function. For example, a protein may be assigned the name Y4 receptor and may be completely unrelated to the disclosed protein of SEQ ID NO:2, having a different function or even be inactive. The critical technical feature encompassed by the substantially identical Y4 receptors must relate the encompassed polypeptide, structurally and functionally to the disclosed protein of SEQ ID NO:2. It is

not clear what critical technical feature the undisclosed amino acids, provide so as to show a written description of the invention in full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing. The specification proposes to discover other members of the genus by using hybridization techniques. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

The specification further fails to identify and describe the regulatory regions essential to the function of the Y4 receptor since the claimed invention currently encompasses the full length, truncated, fusion polypeptides and variants thereof. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus may be highly variant, the disclosure is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 147, 148-151 and 153 rejected under 35 U.S.C. 102(e) as being anticipated by Gerald et al (Ref A)

The applied reference has a common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Gerald et al. teach the rat Y4 receptor expressed in COS-7 cells (Table 4) and a process for determining whether chemical compounds specifically bind to and activates or inhibits a human Y4 receptor . Gerald disclose mammalian cells transfected with a vector adapted for expressing the receptor in the cell and method of obtaining a composition which comprises determining whether a chemical compound binds to a human Y4 receptor (columns 23 and 24). The compound that binds to Y4 receptor is admixed with a carrier, and further, since a pharmacological profile is determined the compound must have contained a pharmaceutically acceptable carrier. Therefore the disclosure of Gerald et al meets the limitation of claims 147, 148 and 151 and 153, absent evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 703-308-9435. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Nirmal S. Basi
Art Unit 1646
November 16, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600